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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,599	06/25/2003	Dae-Kyong Kim	DONGIN1.001AUS	2268

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,599	KIM ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to an isolated cytosolic polypeptide rPLA2 derived from RBC cytosol, classified in class 435, subclass 198.

II. Claims 11-12, drawn to a method for producing a purified cytosolic rPLA2 polypeptide, classified in class 435, subclass 198.

III. Claim 13-19, drawn to an antibody of polypeptide rPLA2, a pharmaceutical composition containing the antibody, and process of making the antibody, classified in class 530, subclass 387.9.

IV. Claim 20, drawn to a pharmaceutical composition containing EA4 compound and a pharmaceutical carrier, classified in class 546, subclass 152.

V. Claim 21-22, drawn to a method of treating disease by using antibody of rPLA2, classified in class 424, subclass 130.1.

VI. Claim 23-24, drawn to a method of treating disease by using EA4, classified in class 546, subclass 152.

The inventions are distinct, each from the other because of the following reasons:

2. The composition containing EA4 compound of Group IV and the proteins of Group I and III, are each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The structure of the chemical compound of Group IV and the proteins of Group I and III each unrelated and distinct, and protein of Group I and III comprise unrelated amino acid sequences. The proteins have other utility besides acting as an antigen to induce the antibodies such as degradation of another protein.

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case Group II, which is a method for producing a purified polypeptide can be used to purify materially different protein such as acetyl-CoA synthetase.

4. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of a protein can be used for the materially different process of detection of a protein by using immunoassaying process.

5. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the chemical compound EA4 which is an inhibitor of rPLA2 also can be used for the induction of cytochrome p450 mRNA and protein, and also to modulates cyp1A1 and cyp1B1 expression.

6. Inventions I and V are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, inventions I which is a polypeptide whereas invention V is a method of treating disease by antibody, are each unrelated and distinct invention as the method of Group V neither makes nor uses the protein of Group I. The polypeptide and method of treating a disease by antibody require separate searches of the prior art.

7. Inventions I and VI are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, inventions I which is a polypeptide whereas invention VI is a method of treating disease by chemical compound, are each unrelated and distinct invention as the method of Group VI neither makes nor uses the protein of Group I. The polypeptide and method of treating a disease by chemical compound require separate searches of the prior art.

8. Inventions II and III are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, inventions II which is a method of producing polypeptide whereas invention III is an antibody are each unrelated and distinct invention as method of producing polypeptide of group II neither makes nor uses antibody of Group III.

9. Inventions II and IV are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, inventions II which is a method of producing polypeptide whereas invention IV is a pharmaceutical composition comprising compound EA4 are each unrelated and distinct invention. The method of Groups II and IV comprise different steps, uses different products and produces different results.

10. Inventions III and VI are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, invention III, which is an antibody whereas invention VI is a method of treating disease by chemical compound, are each unrelated and distinct invention as the method of treating disease by EA4 of Group VI neither makes nor uses antibody of Group III. The antibody and method of treating a disease by chemical compound require separate searches of the prior art.

11. Inventions IV and V are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, inventions IV which is a chemical compound whereas invention V is a method of treating disease by antibody are each unrelated and distinct invention. The compound cannot be made nor used by the method of Group V and compound and method of treating a disease by antibody require separate searches of the prior art.

12. The methods of groups II and V-VI are patentably distinct as they comprise unrelated steps, as different products and produce different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the imitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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